No. 17-1229

In the

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioners,

v.

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* AUSTIN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY

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QUESTIONS PRESENTED

1. Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae Austin Intellectual Property Law Association ("Austin IPLA") is a bar association located in Austin, Texas with approximately 250 members engaged in private and corporate practice across a wide range of industries and technologies. (*See* www.austin-ipla.org.) Austin IPLA members represent both the owners and users of intellectual property. Austin IPLA takes no position on the ultimate outcome of the parties' dispute, particularly whether an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention. Austin IPLA's sole interest is that the integrity of the Patent Act be maintained through consistent interpretation of statutes, doctrines, and intellectual property rights.

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[1] Pursuant to Supreme Court Rule 37.6, *amicus* states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amicus* and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. All parties to this dispute have consented to the filing of this brief.

SUMMARY OF THE ARGUMENT

The Federal Circuit's decision in *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.* leaves unanswered important questions regarding whether Congress intended to modify its understanding of the *quid pro quo* that is at the heart of the patent system. 855 F.3d 1356 (Fed. Cir. 2017). In the absence of express Congressional intent, the Federal Circuit chose to apply its pre-AIA case law to the post-AIA question of whether a sale of an invention, where the sale but not the invention became known to the public, barred patentability under post-AIA 35 U.S.C. § 102(a)(1). Because the AIA drastically shifted the whole patent system—transforming America from a first-to-invent to a first-to-file system, the Federal Circuit's reasoning not to deviate from its pre-AIA precedents may be misplaced.

The Federal Circuit's *Helsinn* decision also leaves unanswered the question of whether purely private sales made under a non-disclosure agreement (NDA), where neither knowledge of the sale or the invention becomes public, are a bar to patentability pursuant to 35 U.S.C. § 102(a)(1). Although this question is not directly before this court, by addressing whether Congress modified its understanding of the quid pro quo of patent law when it shifted America to a first-to-file system, this Court may provide much needed guidance to patent owners, potential licensees, and practitioners.

ARGUMENT

I. The Court Should Decide Whether Congress Intended to Shift Its Understanding of the *Quid Pro Quo* of Patent Law.

By moving the American patent system from first-to-invent to first-to-file, Congress may have also shifted its understanding of the quid pro quo of the patent system such that reliance on pre-AIA "on sale" bar precedent is no longer relevant.

Post-AIA Section 102(a) lists five independent conditions which could bar patentability:

-being "patented"

-being "described in a printed publication"

-being "in public use"

-being "on-sale"

-being "otherwise available to the public."

35 U.S.C. § 102(a)(1). Only the "on sale" condition fails to require public knowledge of the invention to be patented.

These conditions are similar to the conditions in pre-AIA § 102(b), which barred patentability if the invention was:

-"known by others in the country";

-"used by others in the country";

-"patented"; or

-"described in a publication"

"before the invention thereof by the applicant"; or if "more than one year prior to the date of the application," the invention was:

-"patented";

-"described in a printed publication";

-"in public use . . . in this country"; or

-"on sale . . . in this country".

35 U.S.C. § 102(a) and (b) (pre-AIA).

Because of the similarity between the two passages, in reaching its decision in *Helsinn*, the Federal Circuit turned to its pre-AIA precedents. *Helsinn* at 1367, n.7 (approvingly citing to its line of pre-AIA cases holding that even a private sale or offer for sale can be a barring event). The Federal Circuit also approvingly cited treatises that came to the same conclusion. *Id.*

Justifying its approach, the Federal Circuit noted that "[i]f Congress intended to work such a sweeping change to our on-sale bar jurisprudence and 'wished to repeal . . . [these prior] cases legislatively, it would do so by clear language.'" *Id.* at 1371 (citing to *Dir., OWCP v. Perini N. River Assocs.*, 459 U.S. 297, 321 (1983)). However, the Federal Circuit seems to overlook that the AIA as a whole effectuated a sweeping change: transforming the American patent system from a first-to-invent system to a first-to-file system. Because this change was so fundamental, this Court should consider whether Congress needed to accompany it with an express statement of its intention to overrule the Federal Circuit's on-sale bar jurisprudence. At least, this Court should consider

whether the change in systems re-adjusted Congress' understanding of the *quid pro quo* of the Patent Act.

"The disclosure required by the Patent Act is the quid pro quo of the right to exclude." *JEM Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 US 124, 142 (2001) (internal quotations and citations omitted); *see also Kewanee Oil Co. v. Bicron Corp.*, 416 US 470, 480-81 (1974) ("In return for the right of exclusion—this "reward for inventions,"—the patent laws impose upon the inventor a requirement of disclosure.") (citations omitted). The Government thus will not grant a patent unless the inventor discloses his invention to the public, and an inventor may not remove an invention that is already a part of the public domain. *See, e.g.*, 35 U.S.C. § 102(b) (barring a patent if the inventor sold or offered to sell his invention more than one year prior to filing a patent application); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 6 (1966) ("Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.")

Historically, inventors had to choose whether to protect their intellectual property through trade secret or patent law, but generally not both. *See Kewanee*, 416 U.S. at 490-92. Provisions, such as the pre-AIA on-sale bar prevented an inventor from choosing trade secret protection for years and switching to patent protection upon learning that a competitor had independently derived the trade secret. In the first-to-invent system, even if the competitor attempted to patent the invention, the inventor would be protected under the first-to-invent

system, since he would be able to defeat patentability by showing that he had known or used the invention in public first.

By switching to a first-to-file system, where the statute includes the incentive to be the first filed, the policies underlying the first-to-invent system may no longer be relevant. For example, in a first-to-file system where the inventor chose not to disclose his invention in exchange for exclusivity, should the system still reward him by allowing him to invalidate the invention of a second inventor? Or should the system allow him to exploit his invention through secret sales and grant him exclusivity for his invention as long as he is the first to disclose the invention through filing a patent application? Such questions directly implicate whether Congress' has altered the fundamental *quid pro quo* of patent law, and taking into consideration Congress' actions, this Court will help provide clarity to practitioners.

II. The Court Should Decide What Types of Private Agreements are Encompassed by the On-Sale Bar.

The current caselaw does not provide clarity about what types of private agreements would be included in the post-AIA on-sale bar, assuming that private agreements are included at all. This issue is raised by the Question Presented because the agreement at issue was a private Supply and Purchase Agreement that may implicate future products that have not been developed. Thus, under the Federal Circuit's holding in *Helsinn* there is no certainty for patent practitioners or patent owners

about the exact date that future products covered by such an agreement would have a potential on-sale bar.

Up until the Federal Circuit's *en banc* decision in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016), all types of private agreements were bars to patentability. For example, in *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), the court held that a patentee's contract with a supplier to manufacture the product embodying an invention constituted a disqualifying "sale," even though the production activity and the invention remained secret. *See id.* at 1357. In *In re Caveney*, 761 F.2d 671 (Fed. Cir. 1985), the court upheld the application of the on-sale bar to an offer to sell the claimed invention to a single entity, even though the counterparty "kept the claimed invention secret from the purchasing public" and the sale activity was "kept secret from the trade." *Id.* at 674-675.

The question becomes when is "the claimed invention . . . on sale" per 35 U.S.C. § 102(a)(1)? This Court's decision in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998) provides some answers. In *Pfaff*, this Court established a two-prong test for determining whether an invention is "on sale," considering (1) whether the product was the subject of a commercial offer of sale and (2) whether the invention is ready for patenting. *See Pfaff*, 525 U.S. at 67. Therefore, technology which has not been developed yet does not meet this test, since an invention has to be "ready for patenting."

What happens when the decision is made at the company, for example by an engineer at the company, to include the technology that encompasses

the invention in one of the planned future semiconductor chips, and that future semiconductor chip is part of the multi-year agreement with the customer, for example the automotive company. Although no known case addresses this issue, it seems that at this point the invention meets the two-part *Pfaff* test and becomes "on sale" per 35 U.S.C. § 102(a)(1). Therefore, this internal decision to include the technology that includes the invention in the future product either marks a complete bar to patentability under § 102(a)(1), or if 35 U.S.C. § 102(b)(1)(A) applies, starts the ticking of the 1-year clock within which an application for a patent must be filed. It is unclear if these types of agreements, in combination with the decision to include the patented technology as a component of the product, actually put the patented technology on-sale or not.

Other questions regarding what types of private agreements are included in the on-sale bar to patentability also remain. For example, whether a private sales agreement for a product which includes the patented technology as a component, but where the sales agreement does even mention the patented technology, trigger the on-sale bar. Whether there are agreements that would not be bar to patentability when private, but become bars to patentability when they become public? What happens if a company reverses its decision and decides not to include the patentable technology in the future product after an agreement is signed. These questions lead to uncertainty for practitioners.

CONCLUSION

Respectfully submitted by amicus curiae Austin IPLA.

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